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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,642	10/02/1998	AKE LINDAHL	003300-506	8949

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	24

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/155,648	Applicant(s) EITLER ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-99* is/are pending in the application.

4a) Of the above claim(s) *59,60,80,81,83,84,95,96,98 and 99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-58,61-79,82,85,88-94,97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted February 5, 2003 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 55-58, 61-79, 82, 85, 88-94 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 55 is drawn to a composition comprising a) a solvent, which comprising unsaturated fatty alcohol and propylene glycol; and c) a plasticizing agent, which would read on the unsaturated fatty alcohols, or propylene glycol recited in a) (see, the specification, page 8, lines 22-31). The double inclusion of such elements renders the claim indefinite as to the particular amounts of a) and c) recited in the claimed composition. One of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 55-58, 61-79, 82, 85-94 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (U.S. Patent 5,362,497) in view of Wang et al. (U.S. Patent

4,299,828 of record), Copper (U.S. Patent 4,552,872 of record) for reasons set forth in the prior office action.

Response to the Arguments

Applicants' amendments and remarks submitted February 5, 2003 have been fully considered, but are not persuasive for reasons discussed below.

6. Applicants' arguments about the rejection under 35 U.S.C 112, second paragraph is not probative. Particularly, plasticizing agents defined in application is aliphatic acids and alcohols, see page 8, lines 22-31, also see claim 66. Further, the intended function of an ingredient cannot be used to define a compound. The fact is the scopes of ingredients a) and c) are substantially overlapped. The double inclusion of such elements renders the claim indefinite as to the particular amounts of a) and c) recited in the claimed composition. One of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, it is known in the art to use both propylene glycol and fatty alcohol (particularly, oley alcohol) as penetration enhancer in topical application (Yamada et al., Cooper et al.); it is known in the art that fatty alcohol and wax are essential carrier in a tick formulation for corticosteroid, and propylene glycol is useful in the stick formulation. Considered, the cited references as whole, the claimed invention would be obvious as discussed above.

In response to applicants' arguments that Yamada require the presence of superabsorbing polymers, the instant claims, employing transition phrase "including," do not exclude any other ingredients from the claimed composition. Further, Yamada expressly teach the superabsorbing polymer is for absorbing water in the composition to form gel. Take all cited references as a whole, when formulating a composition, wherein the active ingredients is hydrophobic, such as corticosteroid, it would have been prima facie obvious to one of ordinary skill in the art that, water is not required in the composition, as shown in Wang et al., and the superabsorbing polymer would not be required in such formulation. Further, the intended use of otherwise obvious composition would not make the composition patentably distinct since it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161.

In response to applicants' remarks about the amount of wax, note Wang teaches the amount of wax for stick composition is 10-40%, and preferred 15-30%. Further, there is no evidence showing the instant claims produce unexpected results according Cooper, i.e., employ more wax, but not reduce the penetration efficacy.

As the definition of wax, note natural wax is an ester of fatty alcohol and fatty acid. Further, the instant claims do not limit the wax herein to hydrocarbon.

Regarding the remarks about the amount of alkylene glycol, note Yamada teaches that glycol is particularly useful for enhance s transdermal absorption, which may range 1-50% in a transdermal composition. Wang teaches a range or glycol 1-25%, and preferred 2-10%. Take cited reference as a whole, employment of more than 12% of glycol would be obvious for both antimicrobial activity and for transdermal absorption enhance.

8. In summary, the instant claims directed to a therapeutical composition, employ old and well-known ingredients, wherein the amounts specified herein is well within the range taught or suggested in the cited reference. The claims have been properly rejected.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

May 1, 2003